

FLAVORCHEM INT. INC. – NAQADA PACIFIC

PETITION TO USDA INCLUSION OF

FOOD COLOR (ELDERBERRY JUICE CONCENTRATE)

IN NOP NATIONAL LIST

DATE SUBMITTED:

Submitted in duplicate to:
National Organic Standards Board,
 c/o Robert Pooler, Agricultural Marketing Specialist,
 USDA/AMS/TM/NOP, Room 2510-So., Ag Stop 0268, P.O. Box 96456,
 Washington, D.C. 20090-6456.
 Phone: 202/720-3252. Fax: 202/205-7808.
 e-mail: nlpetition@usda.gov.

What Are the Substances for Which a Petition May be Submitted?

Only single substances or ingredients may be petitioned for evaluation. Formulated products cannot appear on the National List. Substances that appear on USDA's current Proposed National List, 65 Fed. Reg.13626-13628 (2000), should not be petitioned for inclusion on the National List.

ALL GUIDING DOCUMENTS AVAILABLE AT:

[HTTP://WWW.AMS.USDA.GOV/NOP/PETITION/PETITIONHOME.HTML](http://WWW.AMS.USDA.GOV/NOP/PETITION/PETITIONHOME.HTML)

1	Petition Category	Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic" or made with organic (specified ingredients).
2	Substance common name:	Elderberry Juice Concentrate
3	Manufacturer's name, address and telephone number:	Gillette Flavors 751 Rahway Avenue Union, NJ 07083 USA
4	Intended or current use of substance:	Used for Color.
5	List the "mode of action" of the substance:	N/A
6	Substance source:	Prepared from depectinized, filtered, unfermented juice of properly sound, clean elderberries by concentration at low temperatures and pressure. The concentrate is derived solely from elderberry juice with no other fruits added. It contains no added sugars, acids, colors, preservatives, or other added materials.
7	Substance processing procedure from basic component(s) to final product:*	N/A
8	Summary of available previous reviews by State or private	N/A

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	certification programs or other:	
9	Information re EPA, FDA and State regulatory authority registrations including reg numbers:	N/A
10	Chemical abstract Service (CAS) number or other numbers:	N/A
11	Substance's physical properties and chemical mode of action; (a) chemical interaction (b) toxicity and environmental persistence (c) impacts of manufacture	(a) n/a (b) n/a (c) n/a
12	MSDS sheet:	N/A
13	National Institute of Environmental Health Studies.	N/A
14	Comprehensive substance research reviews and bibliographies including contrasting positions:	N/A
15	Petition Justification Statement:	Color of food or beverage is one of the first attributes recognized by the senses of the purchaser and consumer of the product.

Division 8/2005
April 1, 2006

Nov. 25, 2005 1:30PM

No. 7070 P. 8/33

Evaluation Criteria for Substances added to the National List

Category 1. Adverse impacts on humans or the environment? Substance Elderberry Juice Concentrate

Question	Yes	No	N/A	Documentation (TAP, petition, regulatory agency, other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]			N/A	
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]			N/A	
3. Is the substance harmful to the environment? [§6517c(1)(A)(i); 6517(c)(2)(A)i]			N/A	
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			N/A	
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]			N/A	
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			N/A	
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			N/A	
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]			N/A	
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]			N/A	
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		No harmful effects are anticipated from this product provided good industrial practices are followed.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		No harmful effects are anticipated from this product provided good industrial practices are followed.
12. Is the substance GRAS when used according to FDA's good manufacturing practices?	X			

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[§205.600 b.5]				
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			N/A	

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 2. Is the Substance Essential for Organic Production? Substance Elderberry Juice Concentrate

Question	Yes	No	N/A	Documentation (LAP, petition, regulatory agency, other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]		X		
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [6502 (21)]			N/A	
3. Is the substance created by naturally occurring biological processes? [6502 (21)]			N/A	
4. Is there a natural source of the substance? [§205.600 b.1]	X			
5. Is there an organic substitute? [§205.600 b.1]		X		
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	X			
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			N/A	
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			
9. Is there any alternative substances? [§6518 m.6]		X		
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A---not applicable.

Category 3. Is the substance compatible with organic production practices?

Substance Elderberry Juice Concentrate

Question	Yes	No	N/A	Documentation (TAP, petition, regulatory agency, other)
1. Is the substance compatible with organic handling? [§205.600 b.2]	X			
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]			N/A	
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			N/A	
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			
5. Is the primary use as a preservative? [§205.600 b.4]		X		
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]				It's primary use is to improve the color.
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;		X		
b. toxins derived from bacteria;		X		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			N/A	
d. livestock parasiticides and medicines?		X		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		X		

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.